Soliciting External Input when Developing CDC Guidelines and Recommendations

Purpose: The purpose of this document is to assist CDC staff in determining when and how to solicit external input on guidelines and recommendations.

Guiding Principles: CDC staff should consider the need for external expertise not found at CDC as well as the extent of strong and diverse stakeholder and public interests and points of view in the issue. Before CDC staff begin the development of guidelines or recommendations that might seek input outside of CDC, some critical considerations include:

- The need to outline a roadmap from start to finish.
- The need to commit to the transparency of the process.
- The need to determine whether to use review and consultation from individuals separately vs. via a group or committee.
- The need to determine whether to use an existing structure for input vs. establishing a new process.
- The need to identify potential conflicts of interest among individuals or organizations providing input.

Frequently Asked Questions

What is considered a guideline or recommendation?

The World Health Organization defines a guideline as "A document that contains recommendations about health interventions, whether they be clinical, public health, or policy interventions. A recommendation provides information about what policy-makers, health care providers, or patients should do." Additional information is available in "Guidelines and Recommendations: A CDC Primer" http://intranet.cdc.gov/od/oads/osq/guide-rec/resources-and-tools.htm

When should CDC staff determine if a guideline or recommendation needs input from outside of CDC?

This decision should be made at the earliest stages of development, and before the process begins. However, the need for external input may be identified later in the process, and the same guiding principles apply. All guidelines should also be entered into the CDC Forecasting Portal as early as possible and external engagement should be noted.

With whom should CDC staff consult with on soliciting external input?

Consultation is encouraged, prior to engaging outside parties, including consideration from the Office of the General Counsel (OGC), the Associate Director for Policy (ADP) office, the Associate Director for Science (ADS) office, at the division or center level. The Management Analysis and Services Office (MASO) may also be consulted if a federal advisory committee is under consideration.

How is input obtained from individuals or groups outside of CDC?

Five common approaches to soliciting input for guidelines and recommendations include:

- 1. Consulting with individual experts who are not U.S. government employees: In some cases, outside consultation with experts adds value or is needed in the development of guidelines. However, CDC staff should use caution when taking this approach and consider a number of factors, including how individuals will be selected, whether the expert will serve in an individual capacity or represent an organization. Further, if individuals will be convened as a group, CDC needs to assure compliance with the Federal Advisory Committee Act. Regardless, exploration and documentation of potential conflicts of interests should be addressed. See the chart below for additional considerations.
- 2. Obtaining peer review required by the Information Quality Act (2000), 44 U.S.C. §3516 and the OMB Peer Review Bulletin: Peer review is used to ensure the science that informs our guidelines and recommendations "meets the standards of the scientific community." ² If dissemination of the scientific information in the guidelines have a predictable and substantial impact on important public policies or private sector decisions, this method is required.
- 3. Soliciting public input: The White House's Open Government Directive instructs agencies to empower the public to influence decisions that affect their lives. A fundamental principle is allowing members of the public to contribute ideas and expertise so policies are made with the benefit of information that is widely dispersed in society. Outside input can be accomplished in a variety of ways, including soliciting public input via a Federal Register Notice, hosting a public webinar, or conducting a focus group. In soliciting public input, CDC needs to assure compliance with the Federal Advisory Committee Act (FACA).

¹ WHO Handbook for Guideline Development http://www.who.int/kms/handbook 2nd ed.pdf

² OMB Bulletin for Peer Review: https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf

- **4. Soliciting input from other U.S. federal agencies:** If expertise is required from other agencies, federal employees may work with other agencies individually or establish a federal workgroup to provide advice on the development of guidelines or recommendations.
- 5. Convening a federal advisory committee: The FACA ensures that advice rendered to an agency is both objective and accessible to the public. A Federal Advisory Committee (FAC) may be required by statute or Presidential directive with specific purposes and functions. FACs may also be established under the authority of an agency head. If an agency convenes a group (that includes individuals external to the federal government) to help inform guidelines or recommendations, that group may be subject to FACA requirements. Groups that include external experts who either are asked for consensus or come to consensus are usually deemed to be subject to FACA.

Depending on the scope and impact of the guidelines or recommendations, CDC may need to obtain input via multiple mechanisms. Most questions arise around the applicability of FACA and whether an opportunity for public review and input is provided. The chart below outlines the advantages and disadvantages of each, along with alternatives, resources, and additional considerations.

Do's and Don'ts of Obtaining Outside Individual Expertise

With limited exceptions, any group that is established or utilized by a Federal agency to provide advice to the agency and that has more than one member who is not a Federal employee, must comply with the FACA. FACA applies to all meetings of such groups, regardless of whether they are held in person or through electronic means.

Regulatory exceptions³ exist for any group that meets with federal officials for the exchange of facts or information or where advice is sought from the attendees on an *individual basis* and *not* from *the group as a whole*.

If you are planning to convene a non-FACA group that includes non-federal individuals to provide the agency with advice:

DO:

- Have a plan for evaluating potential conflicts of interest.
- Use individuals who represent diverse and balanced views on the subject matter.
- Tell individuals that they are being consulted to exchange information and observations and/or to obtain their individual input, and to direct their comments to CDC or the meeting facilitator, not to each other.
- Solicit information or viewpoints as opposed to advice, opinions, or recommendations.
- Solicit information from each individual rather than from an interactive group discussion.
- Focus the participants away from discussions that could lead to collective agreement on a common position.
- If meetings are recurrent, invite different individuals for each meeting and seek their information or viewpoints on varying topics.
- Take into consideration whether the subject matter is high-profile or controversial.
- Consult with the Office of the General Counsel and relevant policy offices.
- Document that you have taken the steps described above.

DON'T:

- Restrict the group to individuals with limited, biased, or narrow viewpoints.
- Establish a static, restricted-membership group.
- Encourage extended interaction between the individual participants.
- Solicit advice, opinions, or recommendations from the group using a strict and narrowly defined structure and purpose.
- Seek to obtain a consensus or to vote on matters entertained by individuals in the group.

³ Other regulatory exceptions also exist, including groups created by non-Federal entities (such as a contractor or private organization), provided that these groups are not actually managed or controlled by the executive branch; groups composed wholly of full-time or permanent part-time officers or employees of the Federal Government and elected officers of State, local, and tribal governments (or their designees) acting in their official capacities in order to exchange views, information, or advice relating to the management or implementation of Federal programs established by statute and that share intergovernmental responsibilities or administration; operational committees, among others. For additional guidance regarding these exceptions, please consult the Office of the General Counsel.

- Represent the advice received as collective advice or as the view of the group.
- Describe the meeting as a committee, task force, or group.

Public Input

Groups of Individual Experts

Advantages

- Efficient if limited expertise is available
- > Targeted

Disadvantages

- > Limited transparency
- No formal vetting for conflicts of interest
- May be perceived as bias if not balanced
- Very limited interactive discussion; perspectives are limited

Alternatives

- > Federal advisory committees can be used if a group needs to be brought together formally
- > Consider peer review for a limited number of experts
- > Consider public comment for additional input
- > Other federal agencies can be consulted

Considerations

Remember to use caution with this approach.

Perception the selection process was biased or an outside group was providing advice (subject to FACA) can call into question the integrity of the guidelines and leave them legally more vulnerable. (See Do's and Don'ts)

Resources

OADS Resources and Tools

http://intranet.cdc.gov/od/oads/osq/guide_rec/resources-and-tools.htm

Office for Consultation

Begin by discussing with your Division or Center ADS and ADP. If additional information is needed OGC and OADS should be consulted.

Advantages

- > Improves transparency
- Multiple ways to collect (e.g., Federal Register Notice, webinar, focus groups)
- Noncontroversial approach

Disadvantages

- In general, requires at least 30 days for comment, plus time for deliberation and response
- May attract special interest groups more than general public (comments may not accurately reflect public opinion)
- May limit expertise provided

Alternatives

- > Federal advisory committees can be used if specific experts need to be gathered in a public process.
- Peer Review also provides a transparent process for collecting and considering comments and limits input to experts on the topic

Considerations

Public input can provide new insight with a different perspective. Enough time must be available for the public to review the document and for the agency to consider the comments.

Resources

Guidelines and Recommendations: a CDC Primer
http://intranet.cdc.gov/od/oads/osq/guide_rec/pdf/GR_P
rimer_Final_July_20_2012a.pdf (Section 7)
CDC Regulations – Federal Register Notices
http://intranet.cdc.gov/od/ocs/cdcreg/registerNotices/index.html

Office for Consultation

Begin by discussing with your Division or Center ADS and ADP. If additional information is needed OGC and OADS should be consulted.

Federal Advisory Committee

Advantages

- Improves transparency
- Conflicts of interest are formally examined
- Allows public input (e.g., via open meetings) along with experts, and is part of the public record

Disadvantages

- Establishing a committee takes time and is often more expensive
- Challenging to establish during an emergency

Alternatives

> If a structured group is not needed, public or individual input may be more efficient

Considerations

There are multiple avenues for engaging a Federal Advisory Committee, including through the use of working groups and subcommittees. Consult with MASO Committee Management and OGC on these options.

Resources

OCIO FACA: http://intranet.cdc.gov/ocio/cdc-policies-organization/federal-advisory-committees/index.html

OGC FAQs:

http://intranet.cdc.gov/ogc/faq/facAct.htm

Office for Consultation

Begin by discussing with your Division or Center ADS and ADP. If additional information is needed. MASO and OGC should be consulted.